APR 18 2014

K133922

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

APPLICANT:	GC MedTech, LLC
TRADE NAME:	GentleCare AR Applicator
COMMON NAME:	Brachytherapy Applicator
CLASSIFICATION NAME:	Remote Controlled Radionuclide Applicator System, 21 CFR 892.5700
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE:	JAQ
PREDICATE DEVICES:	Capri Applicator (K092822)
CONTACT	Colin Carpenter President
DATE:	December 16, 2013

Substantially Equivalent to:

The GentleCare AR Applicator is equivalent in intended use, principal of operation and technological characteristics to the CAPRI Applicator (K092822).

Description of the device subject to premarket notification

The GentleCare AR Applicator is a specialized applicator that is temporarily inserted into the vagina or rectum to facilitate the application of radiation to the target site in the treatment of carcinoma. The GentleCare AR Applicator is provided sterile for single use and is disposable.

Indications for Use

The GentleCare AR Applicator is intended for use with commercially available remote afterloading equipment used during brachytherapy procedures. The multiple lumens of the GentleCare AR Applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.

Materials

All materials used in the manufacture of the GentleCare AR Applicator are suitable for this use and have been used in numerous previously cleared products. The GentleCare AR Applicator was tested per ISO10993 and found to be biocompatible. Testing included the following:

- Cytotoxicity
- Sensitization
- Irritation

Non-Clinical Testing

Product testing was completed and met all of the acceptance criteria. Testing included dimensional measurements, visual inspection, balloon inflation, balloon deflation, balloon burst, bond strength, mechanical and performance.

Performance Data:
All necessary verification and validation testing has been performed for the GentleCare AR Applicator to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the GentleCare AR Applicator is determined by GC MedTech, to be substantially equivalent to existing legally marketed devices.

Trade name	GC MedTech System	CAPRI Applicator	SE Discussion
Product code	JAQ	JAQ	Same product code - JAQ
510k number	K133922	K092822	
Device Classification	II	II	Same – Class II
Device description	The GentleCare AR Applicator is a specialized applicator that is temporarily inserted into the vagina or rectum to facilitate the application of radiation to the target site in the treatment of carcinoma. The GentleCare AR Applicator is provided sterile for single use and is disposable.	The CAPRI Applicator is a specialized applicator that is temporarily inserted into the vagina or rectum to facilitate the application of radiation to the target site in the treatment of carcinoma. The CAPRI Applicator is provided sterile for single use and is disposable	The device description is the same.
Intended Use	Intended for use during brachytherapy procedures. The multiple lumens of the	Intended for use during brachytherapy procedures. The multiple lumens of the CAPRI	Same Indications for Use

	GentleCare AR Applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.	applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.	
Length	Balloon: 10cm; Device: 20cm	Balloon: 8.5cm; Device: 15cm	The small differences in the balloon length does not affect the safety or efficacy of the device's ability to interface with the Afterloader or the delivery of physician controlled therapy
Diameter	6cm	Balloon: 4cm when inflated	The diameter difference does not affect the safety of the device as the inflation of both devices is controlled by the physician with the diameter based on the individual patient's anatomy
Deflated insertion diameter	2cm	3.3cm	The diameters are equivalent for the insertion of the device to the target area
Number of treatment lumens	8: 8 evenly spaced in a single concentric ring	13: 12 evenly spaced in two concentric rings (with six lumens each) surrounding 1 central lumen.	During the treatment planning, the number of lumens are considered in the determination of the treatment plan. The main issue is the concentricity of the treatment lumens which allow the physician to develop an appropriate treatment plan.
Number of expandable baffles	2	2	Same
Location of lumens	Inner baffle	Inner baffle	Same
Inner expandable baffle	Air	Foam	Both inner baffles serve the same purpose – to space the treatment lumens in a circumferential array
Outer expandable baffle	Air	Air	Same
Method of visualization	X-ray	X-ray	Same
Conforming treatment length	10cm	8.5cm	The treatment length is slightly longer for the subject device. As stated previously, the treatment plan is pre-determined by the physician based on the device itself. Therefore, the safety profile of both devices is equivalent.

Compatible Afterloaders	VariSource 200- AL13301000 (channels 1-10) VariSource 200-AL13301001 (channels 11-20) VariSource 200-AL07356001 (channel X) Varian GammaMedplus Nucletron microSelectron Digital microSelectron-HDR	VariSource 200- AL13301000 (channels 1-10) VariSource 200-AL13301001 (channels 11-20) VariSource 200-AL07356001 (channel X) Varian GammaMedplus Nucletron microSelectron Digital microSelectron-HDR	All Afterloaders connect to 6 Fr catheters. The connection interface is also the same.
Method of sterilization	Ethylene Oxide	E-beam	Both devices are supplied sterile. Both methods for sterilization are well known and acceptable for medical devices
Single use	Y	Y	Same
Shelf life	180 days after production	360 days after production	This will be on the product label
Packaging	Paperboard insert in sterile pouch; IFU on 8"x11" paper; both placed inside outer box	Paperboard insert in sterile pouch; IFU on 8"x11" paper; both placed inside outer box	Same
Materials	Biocompatible	Biocompatible	The GC MedTech device was tested to the ISO10993 standard and found to be biocompatible. As the CAPRI device was reviewed and cleared by FDA, we assume the materials of construction for the CAPRI are biocompatible as well.

Conclusion

The substantial equivalence was determined based on the similarity of materials, design, indications for use, packaging and clinical application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 18, 2014

GC Medtech, LLC.
% Gregory Mathison
President
Regulatory Strategies, INC.
3924 Cascade Beach Road
LUTSEN MN 55612

Re: K133922
Trade/Device Name: Gentlecare AR Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: March 17, 2014
Received: March 25, 2014

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133922

Device Name: GentleCare AR Applicator

Indications For Use:

The GentleCare AR Applicator is Intended for use during brachytherapy procedures. The multiple lumens of the GC MedTech device are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)